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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,847	01/22/1999	STUART B. LEVY	PKZ-013CP	5517

959            7590            12/20/2002

LAHIVE & COCKFIELD  
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BOSTON, MA 02109

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/234,847	LEVY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
  - 2a) This action is FINAL.                    2b) This action is non-final.
  - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1,2,4-7 and 30-52 is/are pending in the application.
  - 4a) Of the above claim(s) 2,4-6 and 30-51 is/are withdrawn from consideration.
  - 5) Claim(s) \_\_\_\_\_ is/are allowed.
  - 6) Claim(s) 1,7,29 and 52 is/are rejected.
  - 7) Claim(s) \_\_\_\_\_ is/are objected to.
  - 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

**Final Office Action on the Merits of a Continued Prosecution Application**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

2. **The rejection of claims 1 and 29 under 35 USC 102(b) over Bernardi et al. ('942) is withdrawn.**
3. **The rejection of claims 1 and 29 under 35 USC 102(b) over Bernardi et al. ('384) is withdrawn.**
4. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Su (WO 95/22529).

Su teaches a generic group of 9-(substituted amino)-6-deoxy-5-oxy tetracycline derivatives, such as 9-dimethylaminoacetylamino-6 $\alpha$ -deoxy-5-formyloxy-tetracycline and 9-dimethylaminoacetylamino-6 $\alpha$ -deoxy-5-acetoxy-tetracycline, and their antibiotic activity (see the entire article, especially page 1, line 6 – page 3, line 24; page 10, lines 21-33; page 12, line 23 – page 13, line 8). The compounds and compositions taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

**5. The rejection of claims 1, 7 and 29 under 35 USC 103(a) over Bernardi et al. ('942) is maintained.**

Applicant argues the reference does not teach or suggest the claimed 5,9-substituted tetracycline compounds and that the skilled artisan would not find a teaching or suggestion for replacement of a hydroxyl group at position 5 with any of the claimed 5-substituents. Applicant's argument was considered but not persuasive for the following reasons.

A reference is evaluated based on what it teaches the skilled artisan in the art and not just what is exemplified. The reference teaches R<sub>1</sub> may be hydrogen, hydroxy or acyloxy and, thus, an equivalent between the hydroxyl group exemplified and an acyloxy group. Therefore, the reference teaches and suggests the replacement of the exemplified hydroxyl group at position 5 with an acyloxy group as recited by the claimed invention.

For this reason and those given in previous Office Actions, the rejection of claims 1, 7 and 29 under 35 USC 103(a) over Bernardi et al. ('942) is maintained.

**6. The rejection of claims 1, 7 and 29 under 35 USC 103(a) over Bernardi et al. ('384) is maintained.**

Applicant's argument and the examiner's response are as discussed above in #4.

For this reason and those given in previous Office Actions, the rejection of claims 1, 7 and 29 under 35 USC 103(a) over Bernardi et al. ('384) is maintained.

7. Claims 1 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su (WO 95/22529) in combination.

Su teaches a generic group of 9-(substituted amino)-6-deoxy-5-oxy tetracycline derivatives, such as 9-dimethylaminoacetylarnino-6 $\alpha$ -deoxy-5-formyloxy-tetracycline and 9-dimethylaminoacetylarnino-6 $\alpha$ -deoxy-5-acetoxy-tetracycline, and their antibiotic activity (see the entire article, especially page 1, line 6 – page 3, line 24; page 10, lines 21-33; page 12, line 23 – page 13, line 8).

The instant claims differ from the reference by reciting additional compounds not exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the instant claims, with the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

8. Claims 7 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardi et al. ('942 or '384) in view of Su (WO 95/22529).

Bernardi et al. ('942 or '384) teach a generic group of 5,9-substituted tetracycline derivatives and their therapeutic agents (see the entire articles, especially '**942**, col. 1, formula II and lines 60-64; col. 10, example 10 and '**384**, page 1, formula I and col. 1, lines 10-14; page 4, examples 8 and 9).

The instant claims differ from the reference by reciting compounds having specific ester groups in the 5-position. However, (a) Bernardi et al. teach substitution of

ester groups in the 5-position and (b) Su teaches similar compounds wherein the 5-substituent can be hydroxyl or  $R^4(CH_2)_nC(O)O$  and wherein when n is zero,  $R^4$  can be acetyl, propionyl or cyclobutylcarbonyl (see page 1, formula I and page 3, lines 22-25). The reference also teaches the therapeutic use of the compounds (see especially the Abstract). Su, thus, teaches an equivalent between a hydroxyl group and various ester groups, including those taught by Bernardi, in the 5-position. Therefore, modification of the compounds of Bernardi by substitution of the 5-position with ester groups as taught by Su would have been obvious to the skilled artisan because he would have had the reasonable expectation that said compounds would also be therapeutically active.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

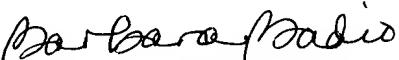
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Radio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
December 19, 2002